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EXAMINER
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ART UNIT	PAPER NUMBER
1723	20

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/462,765

Applicant(s)

GUTMAN ET AL.

Examiner

Matthew O Savage

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 13-42, 66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 13-42, 66 and 67 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

Art Unit: 1723

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification fails to adequately disclose the generic composition associated with the Trademarks "FLUORODYNE" AND "SUPOR".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Concerning claim 6, it is unclear as to what composition the terms "FLUORODYNE" and "SUPOR" imply.

Art Unit: 1723

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 13-34, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall '483 in view of the Filter Reference Guide, and the Pall Selection Guide FLUORODYNE FILTERS (P GRADE), both cited by applicant in the information disclosure statement filed on 2-27-02.

With respect to claim 1, Pall '483 discloses a plastics material housing 1,2 providing an inlet port 4 and an outlet port 6, the material of the housing being such that the assembly can be sterilized by subjecting the interior of the housing to steam under pressure while the exterior of the housing is at atmospheric pressure without damaging the housing (see lines 15-25 of col. 1 which disclose in-line sterilization with steam, and lines 45-60 of col. 6 of which disclose materials including polypropylene having a maximum service temperature of 120 degrees C, and polysulfone having a maximum service temperature of 160 degrees C), a filter element 8 held within the housing, the filter having a central passage extending between first and second ends of the filter medium, the first end of the filter medium being attached to a first end cap 9 of a plastics material at a first joint to close the passage and the second end of the filter being attached to a second end cap 10 of plastics material at a second joint, the second

Art Unit: 1723

end cap 10 providing a fluid connection between the passage and one of the ports. Pall '483 fails to specify the filter medium as being embedded in the end caps, the filter media being of water wettable material, and the first and second end caps as forming water wettable joints with the filter medium. The Filter Reference Guide and the Pall Selection Guide together disclose a filter element including filter medium embedded in end caps wherein the characteristics of the filter medium at the joints are not materially changed (e.g., as implied by the "melt sealed" notation in the Pall Filter Reference Guide), the filter medium being formed of water wettable material (e.g., hydrophilic PVDF, or FLUORODYNE filter media) that inherently includes with first and second ends that form water wettable joints with the filter medium since the references disclose the same combination of materials as disclosed by applicant (e.g., polypropylene end caps and FLUORODYNE filter media) and suggests that such a medium provides superior bacteria and particle removal efficiency in demanding environments (see the "Pall Selection Guide). It would have been obvious to have modified the filter of Pall '483 so as to have included a filter element as suggested by the Filter Reference Guide and Pall Selection Guide in order to provide a filter medium capable of providing superior bacteria and particle removal efficiency in demanding environments.

Concerning claim 2, the Filter Reference Guide discloses heating the end caps to soften the end caps and inserting each one of the first and second ends into the associated end cap while the associated end cap is softened as implied by the term "MELT SEALED".

Regarding claim 3, the Filter Reference Guide and the Pall Selection Guide discloses the first and second end cap plastic material being such that the characteristics of the filter medium adjacent the end cap are not altered by the embedding because the references teach the combination of polypropylene end caps and FLUORODYNE medium.

With respect to claim 6, the Filter Reference Guide and the Pall Selection Guide disclose medium as being FLUORODYNE and the first and second end cap plastic material being formed of polypropylene.

Concerning claim 8, the Filter Reference Guide and the Pall Selection Guide disclose filters that are considered integrity testable the references disclose the same combination of materials as disclosed in the instant specification.

Concerning claim 9, the Filter Reference Guide and the Pall Selection Guide disclose end cap plastic materials having the characteristics as recited in the instant claim because the references disclose the same combination of end cap materials and filter media materials as disclosed in the instant specification.

Regarding claim 13, Pall '483 discloses a housing capable of functioning as disclosed in the instant claim because the housing is formed of the same material as disclosed in the instant specification (see lines 45-60 of col.6).

Concerning claim 14, Pall '483 disclose the housing as being formed of polysulphone.

Regarding claim 15, Pall '483 and the Pall Selection Guide disclose generally annular filter medium, a disk shaped end cap 9, and an annular end cap 10.

As to claim 16, Pall '483 and the Pall Selection Guide disclose pleated filter medium.

Regarding claim 17, the Pall Selection Guide discloses a second end cap having a projection for reception in the associated port of housing.

Concerning claim 18, Pall '483 discloses a housing having first and second end walls (see FIG. 1), the port 2 being in fluid communication with the second end cap 10 in the second end wall, the filter element extending from the second end wall towards the first end wall.

As to claim 19, Pall '483 discloses the housing as having a sidewall (see FIG.1).

Regarding claim 20, Pall '482 discloses the housing as being formed by first and second housing parts 1,2 connected together.

As to claim 21, Pall '483 disclose the first housing part 1 as including the first end wall and the side wall and the second housing part 10 as including the second end wall.

Regarding claim 22, Pall '483 discloses the first housing part and the second housing part as cooperating to clamp the filter element between the housing parts to hold the filter in the housing (e.g., part 16 of the filter being clamped between parts 1 and 2, see FIG. 3).

As to claim 23, Pall '483 discloses the filter element as including first and second oppositely facing clamping surfaces (e.g., defined by part 16), the first housing part 1 bearing against the first clamping surface and the second housing part 2 bearing against the second clamping surface (see FIG.3).

Regarding claim 24, Pall '483 discloses the first and second clamping surfaces as being formed on the second end cap 10 (see FIG. 3).

Concerning claim 25, Pall '483 discloses the first clamping surface as being formed on a flange 16 projecting from the second end cap.

Regarding claim 26, Pall '483 discloses the housing as being formed by first and second housing parts 1,2 connected together, the first and second housing parts cooperating to clamp the filter element between the housing part to hold the filter element in the housing (see FIG.3), the filter element including first and second oppositely facing clamping surfaces (e.g., defined by part 16), the first housing part bearing against the first clamping surface and the second housing part bearing against the second housing surface, the first and second clamping surfaces formed on the second end cap, the second clamping surface being formed on a portion of the second endcap extending around the projection in the case that the Meyering et al filter is employed.

Concerning claim 27, Pall '483 discloses the first housing part as having a peripheral edge 1b remote from the first end wall, the peripheral edge bearing against the flange 16 to force the second clamping surface against a portion of the second end wall of the housing around the port.

Regarding claim 28, Pall '483 discloses the filter medium 43 as being annular and having a curved exterior surface surrounded by a cage 30. In addition, Pall '688 discloses filter medium as being annular and having a curved exterior surface surrounded by a cage 15.

Concerning claim 29, Pall '688 discloses the cage as being formed of the same material as the end caps (see lines 1-6 of col.8).

Regarding claim 30, Pall '483 discloses the housing as including at least one valve (see lines 52-56 of col. 5).

With respect to claims 31-33, Pall '483 fails to specify the valve as being formed of a material that can be heat sterilized, however, such a modification would have been obvious in order to provide an entire filter assembly that could be heat sterilized since the reference discloses that the filter housing that can be heat sterilized (see lines 45-60 of col. 6).

Concerning claim 34, Pall '483 fails to specify the valve as being formed from the recited materials. Pall '483 discloses the housing as being formed of the recited material and teaches that such materials enable the filter to be sterilized. It would have been obvious to have modified the filter of Pall '483 so as to have included the valve as being formed from the same material as the housing in order to enable sterilization of the filter.

Regarding claims 66 and 67, Pall '483 discloses a housing capable of functioning as disclosed in the instant claim because the housing is formed of the same material as disclosed in the instant specification (e.g., the housing formed of polysulfone, see lines 45-60 of col. 6).

Claims 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall '483 in view of the Filter Reference Guide, and the Pall Selection Guide

FLUORODYNE FILTERS (P GRADE), both cited by applicant in the information

disclosure statement filed on 2-27-02, as applied to claim 30 above, and further in view of Wagner.

With respect to claim 35, Pall '483 fails to specify the recited details of the valve. Wagner discloses a valve including annular sleeve 17 surrounding a passage 10 generally circular in cross section as recited in the claim as suggests that such a valve is cheap to construct. It would have been obvious to have modified the combination suggested by Pall '483, Ohtani or Meyering et al so as to have include a valve as suggested by Wagner in order to provide a valve that was cheap to construct.

Concerning claims 36 and 37, Wagner discloses a valve member 12-15 capable of functioning as recited in the instant claim.

Regarding claim 38, Wagner discloses the sleeve 17 and valve member 12-15 as being connected together, the valve member extending into an end of the passage 10 and including a passage 15 capable of functioning as recited in the instant claim.

Concerning claim 39, Wagner discloses the valve as including a mechanism (e.g., sleeve 17 including the threads 19) capable of functioning as recited in the instant claim. Regarding claim 40, Wagner discloses a mechanism capable of limiting axial movement of the valve (e.g., the valve member and stop 21).

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall '483 in view of the Filter Reference Guide, the Pall Selection Guide FLUORODYNE FILTERS (P GRADE), both cited by applicant in the information

Art Unit: 1723

disclosure statement filed on 2-27-02 and Wagner as applied to claim 39 above, and further in view of Schriener.

Concerning claims 41 and 42, Wagner fails to specify the recited pin and slot arrangement, however, such arrangements are well known obvious equivalents in the valve art, as evidenced by Schriener, for increasing the extent of axial motion of a valve member per rotation of the valve member.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nejigaki et al discloses a filter including a polysulphone housing that can be sterilized by an in-line sterilization process.

Applicant's arguments filed 2-27-02 have been fully considered but they are not persuasive.

Applicant's argument that the use of the trademarks "FLUORODYNE" and "SUPOR" in claim 6 is proper is not deemed persuasive since the trademarks correspond to particular chemical compositions that can be subject to change by the manufacturer over time. It is suggested that that applicant amend the claims to list the generic chemical composition corresponding to the trademarks at the time the invention was made.

With respect to the arguments against the rejection of claim 1 over Pall '483 in view of the Filter Reference Guide, and the Pall Selection Guide FLUORODYNE

Art Unit: 1723

FILTERS (P GRADE), applicant argues that the Pall '483 housing formed of propylene is not capable of being sterilized, however, it is held that the housing is capable of such a function since Pall '483 discloses the claimed in-line sterilization procedure (see lines 15-25 of col. 1) and because Pall '483 discloses that polypropylene can be used to form the housing (see lines 45-60 of col. 6). Applicant should note that polypropylene can have a maximum service temperature of 120 degrees C and is thereby capable of being subjected to in-line sterilization procedures. Applicant argues that Pall '483 fails to suggest the combination of a plastic housing that can be steam sterilized (e.g., a polysulfone housing) and a plastic end cap (e.g., a polypropylene end cap) capable of forming a water wettable joint with the filter media since the housing and end cap must be formed of the same material, however, such an argument is not considered persuasive since the reference discloses that the housing can be formed of polysulfone and that the end cap can be formed of polypropylene, and because the reference teaches that housing and end cap do not have to be formed from the same material (see lines 6-11 of col. 5). Finally, one skilled in the art would realize that the housing and end cap would not have to be formed of the same material in the case that the housing of Pall '483 was modified to accept the mechanical tube and socket connection disclosed in the Pall Selection Guide.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew O Savage whose telephone number is 703-308-3854. The examiner can normally be reached on Monday-Friday, 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda W. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Application/Control Number: 09/462,765

Page 13

Art Unit: 1723

M. Savage
Matthew O Savage
Primary Examiner
Art Unit 1723

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April 23, 2003